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10/762,492

01/23/2004

Fredric R. Bloom

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02/07/2007

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EXAMINER

HINES, JANA A

ART UNIT

PAPER NUMBER

1645

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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3 MONTHS

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/762,492

Applicant(s)

BLOOM ET AL.

Examiner

Ja-Na Hines

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-107 is/are pending in the application.
- 4a) Of the above claim(s) 15-76 and 80-107 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 77-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 10-107 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/21/06 8/31/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in the reply filed on October 23, 2006 is acknowledged. Claims 15-76 and 80-107 are withdrawn from consideration. Claims 1-14 and 77-79 are under consideration in this office action.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on February 21, 2006 and August 31, 2004 are of record. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: Non-initialed and non-dated alterations have been made to the oath or declaration with respect to the mailing address for Harry Kim. See 37 CFR 1.52(c).

Specification

4. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-14 and 77-79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a deposit rejection.

The specification lacks complete deposit information for the deposit of an *Escherichia coli* strain having a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294, wherein said isolated *E. coli* do not contain any detectable levels of bacteriophage genetic material from at least one bacteriophage or in the alternative are resistant to infection by one or more bacteriophage types. Also the specification lacks deposit information for deposit JDP674. Because it is not clear that cell lines possessing the properties of the claimed *Escherichia coli* strain are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the claims require the use of the claimed *Escherichia coli* strain, a suitable deposit for patent purposes is required. Without a publicly available deposit of the above cell line, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the cell line is an unpredictable event.

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If a deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of deposit and the complete name and full street address of the depository is required.

If the deposit has not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR §1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent or for a

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period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of a biological material not made under the Budapest Treaty must be filed in the application and must contain:

- 1) The name and address of the depository;
- 2) The name and address of the depositor;
- 3) The date of deposit;
- 4) The identity of the deposit and the accession number given by the depository;
- 5) The date of the viability test;
- 6) The procedures used to obtain a sample if the test is not done by the depository; and
- 7) A statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the *Escherichia coli* cell line described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

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Applicant's attention is directed to In re Lundack, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR §1.801-1.809 for further information concerning deposit practice.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1-14 are rejected under 35 U.S.C. 101 because a *Escherichia coli* strain having a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294, wherein said isolated *E. coli* do not contain any detectable levels of bacteriophage genetic material from at least one bacteriophage or in the alternative are resistant to infection by one or more bacteriophage types as described by the claims is a product of nature. For example, JDP674 strain meets the recited limitations. The claims do not require that the *E.coli* strain be isolated. Insertion of the terms "isolate or purify" would obviate this rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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a) Abbreviations like *E. coli* in claim 1 must be spelled out when used for the first time in a chain of claims.

b) Claim 1 recites the limitation "said isolated *E.coli*" in the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-14, 77 and 79 are rejected under 35 U.S.C. 102(b) as being anticipated by Bloom et al., (WO 00/78925 dated December 28, 2000).

The claims are drawn to *Escherichia coli* having a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294, wherein said isolated *E. coli* do not contain any detectable levels of bacteriophage genetic material from at least one bacteriophage or in the alternative are resistant to infection by one or more bacteriophage types. The dependant claims are also drawn to *E. coli* do not contain any detectable levels of bacteriophage genetic material bacteriophage Wphi, or Mu. The dependant claims are also drawn to *E. coli* not having any detectable levels of bacteriophage from specifically recited bacteriophages; lacking endogenous plasmids; containing selected markers; episomes and have the recite growth rates.

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The claims are also drawn to compositions comprising *Escherichia coli* having a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294, wherein said isolated *E. coli* do not contain any detectable levels of bacteriophage genetic material from at least one bacteriophage such as Wphi or in the alternative are resistant to infection by one or more bacteriophage types.

Bloom et al., teach rapidly growing *E. coli*, such as strain W which lacks endogenous plasmids, or strains BRL3781, BRL3784 and *recA*⁻ derivatives (page 3, lines 23-28). It is noted that the instant specification states that *E. coli* strain W does not contain the genetic material of bacteriophage Wphi and/or does not contain the genetic material of bacteriophage Mu and/or is resistant to infection with T1 phage (page 4, para. [0010]). Thus the art teach the same *E. coli* strain W, therefore strain W does not contain any detectable levels of bacteriophage genetic material from the Wphi or Mu bacteriophage and is resistant to infection by one or more bacteriophages, just as recited by the claims. Furthermore, Bloom et al., teach *E. coli* not lacking endogenous plasmids, just as required by the claims. Bloom et al., teach strains wherein the modification may include alteration of the *recA*⁻ genotype such as *recA1/recA13* or *recA* deletions, a *lacZ*⁻ genotype that allows for alpha complementation such as *lacX74* *lacZΔM15* or other *lacZ* deletions a protease deficient genotype such as Δ lon and/or *ompT*⁻, an endonuclease minus genotype such as *endA1*, a genotype suitable for M13 phage infection by including the F' episome, a restriction negative, modification positive genotype such as *hsdR17*(*r*_K⁻, *m*_K⁺), a restriction negative, modification negative genotype such as *hsdS20*(*r*_B⁻, *m*_B⁻), a methylase deficient genotype such as *mcrA*

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and/or *mcrB* and/or *mrr*, a genotype suitable for taking up large plasmids such as *deoR*, a genotype containing suppressor mutations such as *supE* and/or *supF*. Other suitable modifications are known to those skilled in the art and such modifications are considered to be within the scope of the present invention (pages 4-5, lines 22-6). Thus the art teach *E.coli* containing one or more genotype markers selected from the instantly recited groups, thereby meeting the claim limitations.

Bloom et al., also teach the rapid growing bacteria which have an increased growth rate that is greater than 5%, 10%, 25%, 50%, 75%, 100%, 150%, 200% than the growth rate of the reference microorganism (page 10, lines 14-17). The preferred reference strain is *E.coli* MM294 (ATCC33625). It is noted that Bloom et al., teach the same increased growth rate as compared to the instantly claimed reference strain, thus the claims are taught by Bloom et al. Bloom et al., also teach compositions comprising the rapidly growing microorganisms (page 17, lines 30-32). Thus the reference teaches *E. coli* having a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294, wherein said isolated *E. coli* do not contain any detectable levels of Wphi bacteriophage or in the alternative are resistant to infection by one or more bacteriophage types. Example 3 teaches the construction of BRL3582 a *recA*⁻ *E.coli* W contained in broth. Example 4 teaches *E.coli* W derivatives lacking native plasmids contained in medium.

Thus Bloom et al., teach *Escherichia coli* having a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294, wherein said isolated *E. coli* do not contain any detectable levels of bacteriophage genetic material from at least one

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bacteriophage or in the alternative are resistant to infection by one or more bacteriophage types. Bloom et al., also teach *E. coli* not containing any detectable levels of bacteriophage genetic material bacteriophage Wphi, Mu or other specifically recited bacteriophages; lacking endogenous plasmids; containing selected markers; having episomes, having the recite growth rates and compositions comprising the rapidly growing *E.coli*, just as required by the claims.

Prior Art

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bharathi et al., teach the elimination of broad-host range plasmid vectors in *E.coli* by curing agents. Bhandari et al., teach an *E. coli* host strain. Bloom et al., (US Patent 6,709,852 teach rapid growing microorganisms for biotechnology application. Nagata teach the growth of *E.coli* ATCC 9637.

Conclusion

10. No claims allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Jeffery Siew, can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
January 7, 2007

